

BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

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March 30, 2001

Donald S. Clark Secretary Federal Trade Commission Room H-159 600 Pennsylvania Avenue, NW Washington, D.C. 20580

Re: Generic Drug Study Comments - FTC File No. V000014

Dear Secretary Clark:

The Blue Cross and Blue Shield Association (BCBSA) shares the Federal Trade Commission's (FTC's) goal of ensuring that a competitive market enhances consumer access to lower-cost generic drugs. As such, BCBSA appreciates this opportunity to provide the FTC with additional comments on the Commission's proposed study to investigate how generic drug competition has developed in light of certain provisions in the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act") that govern entry of generic drugs into the market.

BCBSA is a federation of independent, locally operated Blue Cross and Blue Shield Plans that collectively provide health care coverage to 79 million – more than one in four – Americans. Blue Cross and Blue Shield Plans have extensive experience in providing prescription drug coverage through a variety of products and delivery mechanisms designed to meet the quality and value demands of their customers.

As we noted in our initial comments on the Commission's proposed study, the skyrocketing cost of prescription drugs, and the impact of these costs on consumers' access to drugs, is widely acknowledged as one of the leading health care crises in our country today. According to a recent report by the Health Care Financing Administration (HCFA), spending for prescription drugs grew faster than any other category of health care expenditures in 1999 and is expected to be a major factor driving the increase in U.S. health care costs over the next decade. HCFA data indicates that spending for prescription drugs rose nearly 17 percent in 1999, to \$100 billion. During the next four years, drug costs will rise about 15 percent annually, according to HCFA estimates.

Unlike many other countries, the United States relies on a strategy of market competition — not price controls — to keep prescription drugs affordable. As such, BCBSA strongly believes that the federal government should make every effort to ensure that the current regulatory framework supports a truly competitive prescription drug market.

Over the next five years, several of the top selling brand name drugs will go off patent (e.g., Claritin, Pravachol, Prilosec, Prozac, Vasotec, and Zocor). As the FTC noted in the October 17, 2000 Federal Register, innovator companies seeking to protect the market share of their branded drugs "may have an incentive and ability to enter into agreements with would-be generic competitors that would slow or thwart the entry of competing generic drug products" into the market. Such incentives make ensuring a competitive market for prescription drugs an even greater challenge for policymakers.

BCBSA believes that consumers should have access to lower-cost generic drugs as soon as possible. We reiterate our support of the FTC's efforts to re-examine the affect of the 30-month stay and 180-day marketing exclusivity provisions of the Hatch-Waxman Act on the prescription drug market.

BCBSA further supports the FTC's effort to gather information about potentially anticompetitive abuses of the citizen petition process. As the FTC notes, the "cost of filing an improper citizen petition may be trivial compared to the value of securing a delay of a year or more (or possibly as little as a month's delay for a blockbuster drug) in a rival's entry into a lucrative market." Therefore, it is entirely appropriate that the Commission study this aspect of generic competition.

Furthermore, BCBSA supports the inclusion of identifying information regarding the filing of citizen petitions by innovator companies for specific drug products within the scope of this study request. As the FTC made clear in a staff comment to the Food and Drug Administration on this issue, whether the petitioner has received, or will receive, consideration for filing the citizen petition, and from whom, may be important in assessing its likely competitive effect. As such, this information is integral to evaluating the overall impact of the citizen petition process on generic competition.

BCBSA appreciates the opportunity to comment further on the FTC's proposal and looks forward to working with the Commission on this issue. If you have any questions regarding our comments, please contact Christine Simmon at (202) 626-4838.

Sincerely,

Alissa Fox

Executive Director, Legislative Policy Office of Policy and Representation